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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,166	01/02/2003	Werner Mederski	MERCK 2033A	9705

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EXAMINER
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TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/29/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/089,166

Applicant(s)

MEDERSKI ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1624

### DETAILED ACTION

Applicant's preliminary amendment of 05-22-02 has been entered. Claims 1-9 are pending.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 1 and 4 recite the phrase "Compounds of the formula I" which suggests a mixture, or a composition claim rather than a compound claim. Applicant is suggested to replace said phrase with "A compound of the formula I".
- b. Claims 1 and 4 recite the limitation of "solid phase" in the definitions of  $R^2$  and  $R^3$ , which is unclear if such a limitation is part of the final structure of the claimed compounds. From the specification, it appears that "solid phase" is a polymer used in computer-assisted syntheses or mass screening. Thus, it seems that "solid phase" is not a permanent moiety on formula I, and that formula I would be incomplete when the "solid phase" came off.

c. Claim 3, step a) recites "*a compound of the formula I is liberated from one of its functional derivatives...*," which is unclear as to what constitutes "*functional derivatives*".

Formula I has moieties that are substituted with various functional groups. So, would step a) allow for the cleavage of one of those functional groups? If  $R-R^3$  were hydrogen atoms, and  $R^4$  was unsubstituted, would the functional group,  $-NR^2R^3$ , get cleaved then? Or, would "*functional derivatives*" mean some other compounds. Thus, the metes and bounds of "*functional derivatives*" are indefinite as well as the metes and bounds of step a).

d. Claim 3, step c) recites the limitation of "a radical ... is converted into another radical...", which is unclear as to what radical is converted into what. Furthermore, said step recites the phrase "*for example*" which renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

e. Claims 5 and 6 are substantial duplicates of claim 4 because they both recite compounds of the formula I without reciting a narrower limitation. The preamble of "*as glycoprotein lbIX antagonists...*" does not have patentable weight because it does not contribute to the structural change of the compounds of formula I recited in claim 4.

f. Claims 3 and 7 recite the phrase "characterized in that" which is not precise. Applicant is suggested to replace said phrase with the term "wherein".

Art Unit: 1624

g. Claim 7 recites the phrase "one or more" which is indefinite as to what the upper limit is. It is unknown how many compounds of formula I can be incorporated in the same pharmaceutical preparation.

h. **Use Claim:** Claims 8 and 9 provide for the use of "compounds of the formula I", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

**Use Claim:** Claims 8 and 9 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Lack of Written Description:** Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 2 recites two species in items b) and c) which do not seem to have a written description in the specification. It appears that the specification does not describe said species in any example or preferred embodiment.

3. **Lack of Description:** Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The step a) of claim 3 recites "functional derivatives" which does not appear to have a description for. Likewise, the step c) in claim 3 does not appear to have a description for which radical to become which.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by **Bhaduri et. al.** (Indian Journal of Chemistry, 1964, 2(4), pp. 159-61). Bhaduri et. al. disclose a

Art Unit: 1624

substituted quinazolinone compound (“*4(3H)-Quinazolinone, 3-[2-(diethylamino)ethyl]-2-styryl*” – or compound #4 on page 160 – see also CAS print out), which is embraced by the claimed formula I with the following substituents:

- i. R and R<sub>1</sub>, each represents a hydrogen atom;
- ii. Z is absent, n = 1 and m = 1;
- iii. Y is an alkenyl group of 2 carbon atoms;
- iv. R<sup>2</sup> and R<sup>3</sup>, each represents an ethyl group;
- v. R<sup>4</sup> is an unsubstituted phenyl group.

Note, the proviso in both claims does not exclude the quinazolinone compound of Bhaduri et. al.

5. Claims 1, and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated **Houghten et. al.** (US 5,783,577—cited on IDS). On column 5 (lines 22-38), Houghten et. al. (US’577) disclose a subgenus of formula II which allows for many styryl-quinazolinone compounds that read on the claimed formula I with the following substituents:

- i. Z is absent, n + m = 3, 5, or 6 (corresponding to the reference’s R<sup>1</sup>);
- ii. Y is an alkenyl group of 2 carbon atoms (corresponding to the reference’s vinylene);
- iii. R<sup>4</sup> is phenyl, substituted phenyl, etc. (corresponding to the reference’s R<sup>4</sup>);
- iv. R and R<sup>1</sup> (corresponding to the reference’s R<sup>2</sup>), independently represents hydrogen atom, and alkyl group, or halogen, etc.

Art Unit: 1624

The disclosed subgenus has a scope so limited that would allow one skilled in the art to envisage a styryl-quinazolinone compound that falls within the scope of the instant formula I. Furthermore, on columns 25-28, Houghten et. al. provide sufficient guidance for making styryl-quinazolinone compounds by "a library" or solid-phase combinatorial synthesis. Thus, given the disclosed process, one of the ordinary skilled in the art could have made the compounds of the instant formula I for pharmaceutical uses because quinazolinone compounds are known to have various biological properties as disclosed on column 1, lines 30-35 (e.g., hypnotic, sedative, analgesic, anticonvulsant, etc.).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1<sup>st</sup> -03.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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October 27, 2003



ALAN L. ROTMAN  
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